

**Priority question for written answer P-002990/2024
to the Commission**
Rule 144
Christine Anderson (ESN)

Subject: Review and possible revocation of the authorisation for mRNA vaccines in view of new findings

On 28 November 2024, the Paul-Ehrlich-Institut (PEI) published an Excel list with almost one million suspected cases reported with a ‘temporal association’ to COVID-19 vaccinations¹. These reports relate to 235 batches of Comirnaty, the Pfizer/BioNTech vaccine. With regard to Germany, the Paul-Ehrlich-Institut thus provided indications that the Pfizer/BioNTech vaccine may be associated with a batch-dependent increase in the frequency of serious side effects. Similar findings have been reported in other states such as Denmark, The Netherlands, Spain and Czechia.

1. What information does the Commission currently have concerning a batch-dependent increase in the frequency of serious side effects associated with the Pfizer/BioNTech Covid-19 vaccine and has the Commission ordered any investigations in this regard or requested information from the Member States?
2. Was the Commission or the European Medicines Agency (EMA) aware of such information at the time the provisional authorisation was granted, and if not, when did the relevant information come to light and what action was taken in response?
3. Does the Commission intend to initiate a review of the authorisation for the Pfizer/BioNTech vaccine and under what conditions could the authorisation be revoked or restricted?

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¹ https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/rohdaten-sicherheitsberichte/download-xls-uaw-daten-2020-12-27-bis-2023-12-31.html?nn=169638&cms_dlConfirm=true